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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,257	12/21/2001	Peter Krulevitch	IL-10580	6642

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,257	KRULEVITCH ET AL.	
	Examin r.	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 21 December 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 21 Dec. 2001 has been considered and made of record. However, the non-patent literature of Fiedler et al. has not been considered because a copy of the reference has not been provided. Note the cover sheet for the IDS filed 21 Dec. 2001 only lists "(1) U.S. Patent, (1) Foreign Patent".

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference character identified as "22" in the specification is not provided in the drawings. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch et al.(US 5,985,217 or US 6,319,474) in view of Wilding et al.(US 6,184,029).

The references of Krulevitch et al. disclose a microfabricated biopsy/genetic analysis instrument, comprising: a cutter section (35), a specimen chamber (34) located adjacent said cutter section, a specimen treatment section (40) located adjacent said specimen chamber.

While the references Krulevitch et al. disclose that the device includes microchannels for delivering chemicals for treating the specimen, claims 1 and 16 differ by reciting that the device includes a PCR reaction chamber section located adjacent the specimen treatment chamber.

The reference of Wilding et al. discloses that it is known in the art to combine microfabricated sample preparation device with microfabricated analyte detection and/or microfabricated polynucleotide amplification (See column 3, lines 33-43). The reference of

Wilding et al. discloses a microfabricated device that includes a PCR reaction chamber (See Figures 11A and 11B). The reference also discloses that a number of sample sources can be used in the device (See column 22, lines 17-27).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to communicate a PCR reaction chamber with the specimen treatment section for the known and expected result of providing a means recognized in the art for analyzing the sample after being treated and/or processed in the specimen treatment section. Provision of a PCR reaction chamber allows verification of the specimen by amplification and detection of the nucleic acid contained in the sample tissue. Nucleic acid verification would not be capable with the optical system currently disclosed by the references of Krulevitch et al.

With respect to claims 2-4, the references of Krulevitch et al. disclose cutting edge (35) and tapered opening (34) made of a silicon substrate.

With respect to claims 5, 6 and 9, the references of Krulevitch et al. disclose the use of "another" member (32) made of glass. The reference of Wilding et al. also discloses the use of glass as a substrate (See column 8, lines 38-53). As a result, it would have been obvious to provide the microchannels required for adding reagents and/or moving the sample within the device and PCR reaction chamber within substrate (32) of the Krulevitch et al. reference for the known and expected result of using a single substrate for providing the microfluidic channels and chambers suggested by the combination of the references discussed above since the reference of Wilding et al. discloses a similar means of manufacture as that disclosed by the primary references.

With respect to claim 7, the references of Krulevitch et al. disclose a fluid inlet (39) and microchannel (40).

With respect to claims 8 and 19, the references of Krulevitch et al. disclose an optical analysis device (47).

With respect to claim 10, the reference of Wilding et al. discloses that the PCR reaction chamber includes an outlet for post-amplification detection.

With respect to claims 11, 12 and 18, as shown in Figures 11a and 11b of the Wilding et al. reference, the PCR reaction chamber (222A) has a width or cross-section that is greater than the channels and/or chambers upstream to the PCR reaction chamber.

With respect to claims 13 and 14, whether or not the PCR treatment chamber is integral or separate from the sample preparation chamber would have been merely an obvious matter in design choice since the step of making an element integral or separable is not deemed to be a patentably distinct improvement.

With respect to claim 15, the references of Krulevitch et al. disclose both the cutter section (35) and the specimen holding or treatment section formed on the same substrate (31).

With respect to claim 17, whether the treatment zones of the device are formed on a single substrate or plural substrates would have been an obvious matter in design choice based merely on the means for manufacture of the device. Etching would involve two substrates while machining could produce the device on a single substrate.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,985,217 in view of Wilding et al.(US 6,184,029). Claims 1-15 of U.S. Patent 5,985,217 encompass a microfabricated biopsy/genetic analysis instrument, comprising: a cutter section, a specimen chamber located adjacent said cutter section, a specimen treatment section located adjacent said specimen chamber.

While the claims disclose that the device includes microchannels for delivering chemicals for treating the specimen, claims 1 and 16 differ by reciting that the device includes a PCR reaction chamber section located adjacent the specimen treatment chamber.

The reference of Wilding et al. discloses that it is known in the art to combine microfabricated sample preparation device with microfabricated analyte detection and/or microfabricated polynucleotide amplification (See column 3, lines 33-43). The reference of Wilding et al. discloses a microfabricated device that includes a PCR reaction chamber (See Figures 11A and 11B). The reference also discloses that a number of sample sources can be used in the device (See column 22, lines 17-27).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to communicate a PCR reaction chamber with the specimen treatment section for the known and expected result of providing a means recognized in the art for analyzing the sample after being treated and/or processed in the specimen treatment section. Provision of a PCR reaction chamber allows verification of the specimen by amplification and detection of the nucleic acid contained in the sample tissue. Nucleic acid verification would not be capable with the optical system currently disclosed by the references of Krulevitch et al.

With respect to claim 10, the reference of Wilding et al. discloses that the PCR reaction chamber includes an outlet for post-amplification detection.

With respect to claims 11, 12 and 18, as shown in Figures 11a and 11b of the Wilding et al. reference, the PCR reaction chamber (222A) has a width or cross-section that is greater than the channels and/or chambers upstream to the PCR reaction chamber.

With respect to claims 13 and 14, whether or not the PCR treatment chamber is integral or separate from the sample preparation chamber would have been merely an obvious matter in design choice since the step of making an element integral or separable is not deemed to be a patentably distinct improvement.

With respect to claim 15, the references of Krulevitch et al. disclose both the cutter section (35) and the specimen holding or treatment section formed on the same substrate (31).

With respect to claim 17, whether the treatment zones of the device are formed on a single substrate or plural substrates would have been an obvious matter in design choice based merely on the means for manufacture of the device. Etching would involve two substrates while machining could produce the device on a single substrate.

8. Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17 of U.S. Patent No. 6,319,474 in view of Wilding et al.(US 6,184,029). Claims 1-19 are obvious over claim 17 and the reference of Wilding et al. for the same reasons as set forth with respect to the combination of Claims 1-15 of U.S. Patent '217 and Wilding et al. set forth above.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006 (after 12/16/03, 571-272-1269). The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB